भारतीय मानक
Indian Standard

IS 13141 : 2023

न्यूरोसर्जरी के लिए लेक्सेल का रोन्जेउर

(पहला पुनरीक्षण)

Leksell's Rongeur for Neurosurgery

(First Revision)

ICS 11.040.30

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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

November 2023 **Price Group 3**

Neurosurgery Instruments, Implants and Accessories Sectional Committee, MHD 07

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Neurosurgery Instruments, Implants and Accessories Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was originally published as IS 13141 : 1991 ‘Neurosurgical Instruments — Leksell’s Rongeur — Specification’. This first revision includes minor changes in references to incorporate the updated designation of steel and the currently used methods of test corrosion resistance. After publication of this standard, IS 13141 : 1991 stands withdrawn.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

Indian Standard

LEKSELL’S RONGEUR FOR NEUROSURGERY

(First Revision)

1 SCOPE

This standard specifies dimensional and other requirements for Leksell’s pattern, double action rongeur used in neurosurgery.

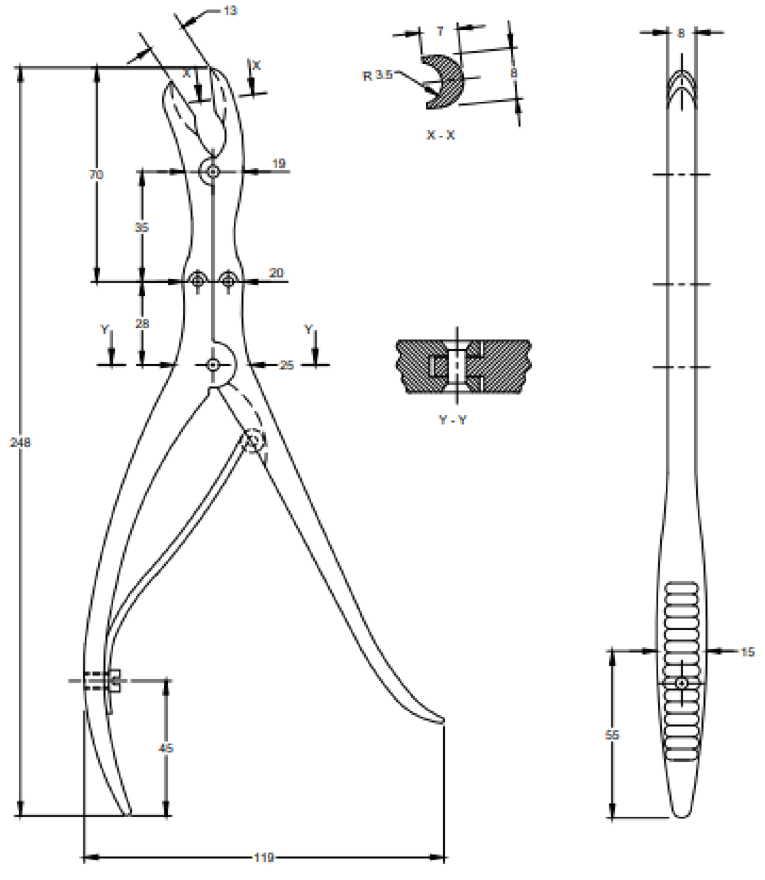
2 REFERENCES

The standard given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

IS No.	*Title*
IS 6603 : 2001	Stainless steel bars and flats — Specification (*first revision*)
IS 7531 : 1990	Methods for testing of corrosion resistance of stainless steel surgical instruments (*first revision*)

3 SHAPE AND DIMENSIONS

3.1 The shape and dimensions of Leksell’s rongeur shall be as shown in Fig. 1.



ALL DIMENSIONS IN MILLIMETRES.
FIG. 1 LEKSELL’S RONGEUR

3.2 The diameter at the tip the rongeur shall be 4 mm, 6 mm and 8 mm. The corresponding width at the cross section XX shall be 6 mm, 8 mm and 10 mm.

3.3 Permissible tolerance on various dimensions are as given below:

a) ± 0.1 mm on dimensions up to 2.0 mm;
b) ± 0.2 mm on dimensions above 2.0 mm and up to 5.0 mm;
c) ± 1.0 mm on dimensions above 5.0 mm and up to 20.0 mm;
d) ± 1.5 mm on dimensions above 20.0 mm and up to 50.0 mm; and
e) ± 2.0 mm on dimensions above 50.0 mm.

4 MATERIAL

4.1 Jaws

Jaws shall be made of stainless steel conforming to Designation X40Cr13 of IS 6603 : 2001.

4.2 Arms and Springs

Arms and springs shall be made of stainless steel conforming to Designation X30Cr13 of IS 6603 : 2001.

4.3 Screws

Screw shall be made of stainless steel conforming to X20Cr13 of IS 6603 : 2001.

5 REQUIREMENTS

5.1 Workmanship

The rongeur shall be of symmetrical and balanced construction. The screws shall be well formed and shall have regular threads. The joints shall work smoothly. The spring action shall be smooth. It shall be neither too hard nor too slack. The compound action shall be smooth and free from jerks. The cutting edges shall be sharp, uniform and free from nicks. They shall match evenly when the jaws are closed. The arms of the rongeur shall be either matt finished on knurled. Grooves on the outer surface of the handle shall be shallow and gently rounded off, so that these do not hurt the fingers while in use.

5.2 Heat Treatment and Hardness

Various components of the rongeur shall be suitably hardened and tempered to give a hardness of:

a) 500 HV to 600 HV for jaws;
b) 420 HV to 470 HV for arms and springs; and
c) 290 HV to 320 HV for screws.

5.3 Surface Condition

All surfaces shall be free from pores, crevices and grinding marks. The rongeur shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

5.4 Surface Finish

The surface finish shall be one of, or a combination, of the following:

a) mirror polished; and
b) Reflection-reducing, for example satin finish, matt black finish.

NOTES

1 The satin finish should be affected by an appropriate procedure, such as grinding, brushing electro polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grind marks, resulting in a mirror finish. The mirror finish should be affected by an appropriate procedure such as polishing, brushing, electropolishing, and mirror buffing.

5.5 Passivation and Final Treatment

The rongeur shall be treated by a suitable passivation process.

NOTES

1 Example of methods of passivation are by electro polishing or by treating with 10 percent (v/v).

2 Solution for not less than 30 minutes at a temperature of not less than 10 °C and not exceeding 60 °C. The rongeur should then be rinsed in water and dried in hot air.

3 If the joints are lubricated, the lubricant should be non-corrosive and suitable for medical application according to Indian pharmacopoeia.

6 TESTS

6.1 Performance Test

Cut a piece of teakwood of 3 mm to 4 mm thickness five times with the instrument.

On completion of the test, the cutting edges and the instrument as a whole shall not show any sign of damage.

6.2 Rigidity Test

A compressive force of 110 N shall be applied to the rongeur arms at a distance of 75 mm from free ends in such a manner that it tends to press the arms together. The maximum force shall be attained gradually and shall act for two minutes. On completion of the test, the rongeur shall show no sign of damage.

6.3 Corrosion Resistance Test

The rongeur shall show no sign of corrosion when tested in accordance with IS 7531 : 1990.

7 MARKING

7.1 Each rongeur shall be suitably marked by etching or otherwise with the following:

a) Indication of the source of manufacture; and
b) The word ‘Stainless steel’ or Letter “SS”.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standad may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

8 PACKING

Each rongeur may be wrapped in a moisture- proof paper or put in a polyethylene bag and packed in cardboard cartons. The rongeur may also be packed as agreed to between the purchaser and the supplier.

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This Indian Standard has been developed from Doc No.: MHD 07 (20242).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices: *Telephones*

Central : 601/A, Konnectus Tower -1, 6th Floor,
DMRC Building, Bhavbhuti Marg, New
Delhi 110002 — 2323 7617

Eastern : 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V,
Salt Lake, Kolkata, West Bengal 700091 — 2367 0012, 2320 9474

Northern : Plot No. 4-A, Sector 27-B, Madhya Marg,
Chandigarh 160019 — 265 9930

Southern : C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113 — 2254 1442, 2254 1216

Western : Plot No. E-9, Road No.-8, MIDC, Andheri
(East), Mumbai 400093 — 2821 8093

Branches : AHMEDABAD. BENGALURU. BHOPAL. BHUBANESHWAR. CHANDIGARH. CHENNAI. COIMBATORE. DEHRADUN. DELHI. FARIDABAD. GHAZIABAD. GUWAHATI. HIMACHAL PRADESH. HUBLI. HYDERABAD. JAIPUR. JAMMU & KASHMIR. JAMSHEDPUR. KOCHI. KOLKATA. LUCKNOW. MADURAI. MUMBAI. NAGPUR. NOIDA. PANIPAT. PATNA. PUNE. RAIPUR. RAJKOT. SURAT. VISAKHAPATNAM.

Published by BIS, New Delhi